Response

REMARKS

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 2 and 5-9 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity.

Claim 2 has been rejected as the recitation "over the entire length thereof" is allegedly unclear. This recitation has been removed from Claim 2.

Claim 2 has been rejected as allegedly being indefinite in the recitation of "stringent conditions." Claims 5-9 have been similarly rejected as being dependent on Claim 2; however, Claims 5-9 are not dependent on Claim 2. It is therefore believed that the rejection of Claims 5-9 is an error. Claim 2 has been amended to recite that stringent conditions comprise conditions comprise include overnight incubation at 42 °C in a solution comprising: 50% formamide, 5xSSC (150mM NaCl, 15mM trisodium citrate), 50 mM sodium phosphate (pH 7.6), 5x Denhardt's solution, 10 % dextran sulfate, and 20 microgram/ml denatured, sheared salmon sperm DNA; followed by washing the filters in 0.1x SSC at about 65 °C, as recited on page 6 of the specification.

It is believed that the foregoing amendments overcome the rejection under 35 U.S.C. § 112, second paragraph. Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-9 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner has also rejected claims 1-9 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention.

The first paragraph of § 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification

is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, it is a tenet of patent law that an applicant need not teach what the skilled artisan already knows. Instead, it is preferred that an applicant "omit what is known in the art." *Hybritech Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986). With this standard in mind, the issues raised by the Examiner are discussed below.

The Examiner has indicated that the specification is enabling for an isolated polynucleotide sequence (DNA or RNA) of SEQ ID NO: 1, a sequence that is at least 95% identical to SEQ ID NO: 1 over the entire length and encoding a polypeptide with methionyl tRNA synthetase activity, vectors and host cells comprising the same, a process of expressing and producing the encoded polypeptides, the polypeptide of SEQ ID NO: 2, and a polypeptide 95% identical to the entire sequence of SEQ ID NO: 2 with methionyl synthetase activity.

The rejection alleges the specification does not reasonably provide enablement for any variant of a polynucleotide sequence (DNA or RNA)/polypeptide of SEQ ID NO:1/SEQ ID NO: 2 or any polynucleotide (DNA or RNA)/polypeptide that is at least 95% or more identical to any segment of SEQ ID NO:1 or SEQ ID NO: 2. Claims 1 and 2 have been amended to remove references to variants and fragments/segments.

The rejection alleges that the specification does not reasonably provide enablement for claim 2(i). Claim 2(i) has been amended to recite specific hybridization conditions.

The rejection further alleges that the specification is enabling for an antibody immunospecific for the polypeptide of SEQ ID NO: 2, but does not reasonably provide enablement for all antibodies immunospecific for any variant of the polypeptide of SEQ ID NO:2 or any polypeptide that is at least 95% or more identical to any fragment of SEQ ID NO: 2. Claim 3 has been amended to recite an antibody immunospecific for the polypeptide of SEQ ID NO: 2.

The rejection alleges that Claims 2 and dependent claims 3, and 5-9 are so broad as to encompass any DNA having a polynucleotide sequence that in its sequence comprises a sequence that shows 95% or more identity to SEQ ID NO: 1 with or without methionyl synthetase activity or any variant of the polynucleotide (DNA or RNA) which is at least 95% or more identical to any fragment of SEQ ID NO: 1 with or without methionyl synthetase activity. The rejection similarly alleges that claim 1 encompasses sequences that are larger and smaller fragments of SEQ ID NO:2 without methionyl synthetase activity.

The rejection further alleges that antibodies immunospecific to all of said polypeptides variants is beyond the scope enabled by the specification.

Claims 1 and 2 have been amended to remove references to fragments and variants. Claim 2(i) has been amended to provide specific hybridization conditions. Futhermore, claims 1 and 2 have been amended to recite that the polypeptides have, or the polynucleotides encode polypeptides which have, methionyl tRNA synthetase activity. This recitation provides a correlation between structure and function.

Claim 3 has been amended to recite an antibody immunospecific for the polypeptide of SEQ ID NO: 2.

The rejection further alleges that the transition "comprising" renders the claims unduly broad in regards to polynucleotides, polypeptides, and antibodies. Applicant respectfully disagrees. The Board of Patent Appeals and Interferences recently stated that "the transitional term 'comprising' does not allow for internal alterations (e.g. insertions or deletions) of the nucleotide sequences set forth in [specific SEQ ID NOs.], but instead only allows for the addition of nucleotides or other molecules at either end of the nucleotide sequences . . . ." *Ex parte Fisher* 72 USPQ 1020, 1022 (Bd. Pat. App. Int. 2004). *See also id.* at 1030. The Board held that the disclosure of specific SEQ ID NOs. provided "adequate" written description of the nucleic acid molecules, including molecules with "other molecules attached to either, or both of their 5' or 3' ends." *Id.* at 1030. Applicant therefore submits that the specification is enabled for the specific polynucleotides and polypeptides in claims 1-3, and that the transition "comprising" does not unduly broaden the scope of the claim.

The rejection further alleges that the specification does not contain any disclosure of the function of all DNA sequence variants of SEQ ID NO: 1 or all variants of the polypeptide of SEQ ID NO: 2; and that the genus of polynucleotides/polypeptides that comprise these above

molecules is a large variable genus with the potentiality of encoding many different proteins, including functionally unrelated polynucleotide/polypeptides, including partial polynucleotide/polypeptides sequences.

Claims 1 and 2 have been amended to remove recitations to fragments and variants. Furthermore, claims 1 and 2 have been amended to recite that the polypeptides have, or the polynucleotides encode polypeptides which have, methionyl tRNA synthetase activity. This recitation provides a correlation between structure and function.

Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 102

The Examiner has rejected Claims 1-9 under 35 U.S.C. § 102(a) as being anticipated by Ruben et al., U.S. Patent Application Publication No. 2003/0109690 A1. The Examiner has also rejected Claims 1, 2, 5-9 35 U.S.C. 102(b) as being anticipated by Martinis et al; U.S. Pat. No. 5,798,240. The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted).

The rejection alleges that Ruben et al. disclose a sequence showing 95.4% best local similarity to the region between 695-1061 of SEQ ID NO: 1 of the instant application. Ruben, et al. contains 8564 sequences, but the specific sequence alleged was not provided in the rejection. Applicants request that the specific SEQ ID NO: for the allegedly similar sequence of Ruben be provided so that applicant can assess the relevance of the sequence independently.

The rejection alleges that Martinis et al disclose the polynucleotide sequence of a mycobacterial tRNA synthetase gene, vectors and host cells carrying said sequence, and polypeptides obtained by expressing the same, and would be encompassed within the scope of variants of SEQ ID NOS: 1 and 2 therefore anticipate the sequences claimed in the instant application. Again, no specific SEQ ID NO: from Martinis, et al. was provided. Applicants request that the specific SEQ ID NO: for the allegedly similar sequence of Martinis be provided

so that applicant can assess the relevance of the sequence independently. Applicant notes, however, that the recitation of "variants" has been removed from Claims 1 and 2.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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